UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION,

This document relates to: *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.* Case No. 18-op-45090

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

JURY TRIAL DEMANDED

<u>DEFENDANTS MALLINCKRODT LLC AND SPECGX LLC'S ANSWER TO PLAINTIFFS' CORRECTED SECOND AMENDED COMPLAINT</u>

Defendants Mallinckrodt LLC and SpecGX LLC ("Mallinckrodt"), by and through their undersigned counsel, submit the following Answer to Plaintiffs' Corrected Second Amended Complaint ("SAC"), ECF No. 513. Except as expressly admitted herein, all allegations are denied, including, without limitation, the headings, tables, subheadings, and footnotes contained therein. Mallinckrodt hereby answers the numbered paragraphs of the SAC as follows. Mallinckrodt expressly reserves the right to supplement or amend this Answer as may be necessary.

1. Paragraph 1 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

INTRODUCTION

- 2. No answer is required to Paragraph 2 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations in Paragraph 2.
- 3. No answer is required to Paragraph 3 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 3 and therefore denies the allegations. To the extent "[m]anufacturers" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 3.
- 4. No answer is required to Paragraph 4 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or

¹ Mallinckrodt plc is an Irish company that is not subject to personal jurisdiction in the United States. Mallinckrodt plc recently waived service pursuant to the Court's November 9, 2018 Order and has filed a motion for leave to file a motion to dismiss the SAC for lack of personal jurisdiction. Accordingly, Mallinckrodt plc does not join this answer. Should it become necessary at a later date, Mallinckrodt plc will file an answer and affirmative defenses.

information to form a belief about the truth of the allegations in Paragraph 4 and therefore denies the allegations.

- 5. No answer is required to Paragraph 5 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 5 and therefore denies the allegations.
- 6. No answer is required to Paragraph 6 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations. Mallinckrodt states that its opioid medications carry certain well-known and disclosed risks, which are set forth in the FDA-approved warning labels for those medications. Answering further, Mallinckrodt denies any characterization of the unsourced statements from the American Society of Addiction and CDC that are inconsistent with their meaning when read in their entirety and in context.
- 7. No answer is required to Paragraph 7 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 7 and therefore denies the allegations.
- 8. No answer is required to Paragraph 8 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 8 and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the speech of Robert Anderson quoted in Paragraph 8 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that speech or its meaning.

- 9. Paragraph 9 asserts legal conclusions and relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.
- 10. Paragraph 10 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 10.
- 11. Paragraph 11 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 11.
- 12. Paragraph 12 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 12.
- 13. Paragraph 13 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 13.

- 14. Paragraph 14 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 14.
- 15. Paragraph 15 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Manufacturing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 15.
- 16. No answer is required to Paragraph 16 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations and therefore denies the allegations.
- 17. Paragraph 17 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 17.
- 18. Paragraph 18 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 18. Mallinckrodt respectfully

refers the Court to the websites quoted in Paragraph 18 for their complete content, which speaks for itself, and denies any inaccurate characterizations of that website or its meaning.

- 19. Paragraph 19 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 19. Mallinckrodt respectfully refers the Court to the letter cited in Paragraph 19 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that letter or its meaning.
- 20. The first sentence of Paragraph 20 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. With respect to the second and third sentences, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the roles and responsibilities of Plaintiff governmental entities. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 20.
- 21. Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations concerning Plaintiff governmental entities and therefore denies the allegations. The second and third sentences of Paragraph 21 include legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 21.

- 22. Paragraph 22 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 22.
- 23. No answer is required to Paragraph 23 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations and therefore denies the allegations.
- 24. Paragraph 24 contains Plaintiffs' characterization of their legal claims to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations and therefore denies the allegations.

JURISDICTION AND VENUE

- 25. Paragraph 25 asserts legal conclusions regarding the Court's jurisdiction to which no answer is required. To the extent an answer is required, Mallinckrodt denies these allegation, as the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et. seq.*, does not provide Plaintiffs with a cause of action against Mallinckrodt.
- 26. Paragraph 26 asserts legal conclusions regarding the Court's jurisdiction that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 26.

27. Paragraph 27 asserts legal conclusions regarding venue to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations and therefore denies the allegations.

PARTIES

I. PLAINTIFFS

- 28-54. No answer is required to Paragraphs 28-54 as they contain no allegations against Mallinckrodt. To the extent a response is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraphs 28-54 and therefore denies the allegations.
- 55. Paragraph 55 consists of Plaintiffs' characterization of the "Plaintiffs" in this action to which no answer is required. To the extent an answer is required, Mallinckrodt admits that Summit County and the City of Akron are plaintiffs in the instant action.
- 56-57. No answer is required to Paragraphs 56-57 as they contain no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraphs 56-57 and therefore denies the allegations.
- 58-61. Paragraphs 58-61 assert legal conclusions and relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.
- 62. Paragraph 62 asserts legal conclusions and relates to Plaintiffs' characterizations of their claims and thus no answer is required. Furthermore, Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1961(3) and 18 U.S.C. § 1964, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

II. <u>DEFENDANTS</u>

A. Marketing Defendants

63. Paragraph 63 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 63.

1. Purdue Entities

64-70. No answer is required for Paragraphs 64-70 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

2. Actavis Entities

71-73. No answer is required for Paragraphs 71-73 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

3. Cephalon Entities

74-77. No answer is required for Paragraphs 74-77 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

4. <u>Janssen Entities</u>

78-88. No answer is required for Paragraphs 78-88 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

5. Endo Entities

89-94. No answer is required for Paragraphs 89-94 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

6. <u>Insys Therapeutics, Inc.</u>

95-99. No answer is required for Paragraphs 95-99 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

7. <u>Mallinckrodt Entities</u>

100. Mallinckrodt admits that Mallinckrodt plc is an Irish public limited company headquartered in the United Kingdom, which is an indirect holding company and the ultimate parent company of Mallinckrodt LLC and SpecGx LLC. Answering further, Mallinckrodt LLC and SpecGx LLC are both Delaware limited liability companies headquartered in St. Louis, Missouri. Answering further, "Mallinckrodt" (as limited to Mallinckrodt LLC and SpecGX LLC) admits that it manufactured and sold FDA-approved pharmaceutical products, including opioid medications. Mallinckrodt denies that it manufactured pharmaceutical products in Summit County. Mallinckrodt denies the remaining allegations in Paragraph 100.

- 101. Mallinckrodt admits that it lawfully manufactured FDA-approved medications Exalgo, Roxicodone, and Xartemis XR and that Mallinckrodt marketed Exalgo and Xartemis XR. Answering further, Mallinckrodt states that the FDA approvals and indications for its products speak for themselves and respectfully refer the Court to the FDA-approved labeling. Mallinckrodt denies that it "promoted its branded opioid products with its own direct sales force" insofar as the terms "promot[ed]" and "direct sales force" are vague and undefined. Mallinckrodt denies the remaining allegations in Paragraph 101.
- 102. With respect to the first sentence of Paragraph 102, Mallinckrodt denies Plaintiffs' characterizations of Mallinckrodt's business motivations or business. Mallinckrodt admits the remaining allegations in Paragraph 102.
- 103. Mallinckrodt denies that it "operates a vertically integrated business in the United States" insofar as the phrase "vertically integrated business" is vague and undefined. Mallinckrodt admits that it manufactures opioid medications at its facility in Hobart, New York. Answering further, Mallinckrodt admits that it sells opioid medications to wholesale drug distributors. Mallinckrodt denies the remaining allegations in Paragraph 103.
 - 104. Admitted.
- 105. Paragraph 105 asserts a legal conclusion to which no answer is required. Mallinckrodt admits that it contracted with certain doctors to serve as speakers or to provide consulting services and that it lawfully made certain payments in connection with these services. Mallinckrodt denies the remaining allegations in Paragraph 105.
- 106. Paragraph 106 consists of Plaintiffs' characterization of the "Defendants" in this action to which no response is required.

B. Distributor Defendants

107. No answer is required to Paragraph 107 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

1. AmerisourceBergen Drug Company

108. No answer is required to Paragraph 108 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

2. Anda, Inc.

109. No answer is required to Paragraph 109 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

3. <u>Cardinal Health, Inc.</u>

110. No answer is required to Paragraph 110 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

4. CVS Health Corporation

111. No answer is required to Paragraph 111 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs'

allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

5. Discount Drug Mart, Inc.

112. No answer is required to Paragraph 112 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

6. <u>HBC Service Company</u>

113. No answer is required to Paragraph 113 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

7. Henry Schein Entities

114-119. No answer is required to Paragraphs 114-119 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations

8. <u>McKesson Corporation</u>

120-121. No answer is required to Paragraphs 120-121 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

9. Miami-Luken, Inc.

122. No answer is required to Paragraph 122 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

10. Prescription Supply, Inc.

123. No answer is required to Paragraph 123 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations

11. Ride Aid Entities

124. No answer is required to Paragraph 124 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations

12. Walgreen Boots Alliance, Inc.

125. No answer is required to Paragraph 125 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

13. Walmart, Inc.

126-128. No answer is required to Paragraphs 126-128 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to

Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

C. Agency and Authority

129. Paragraph 129 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 129.

FACTUAL ALLEGATIONS

III. FACTS COMMON TO ALL CLAIMS

D. Opioids and Their Effects

- 130. No answer is required to Paragraph 130 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt admits that "opioid' refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids" and that "Natural opioids are derived from the opium poppy." Mallinckrodt denies Plaintiffs' characterization of the "most significant" effects of opioids as vague and undefined.
- 131. No answer is required to Paragraph 131 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt admits that opium alkaloids, including morphine, codeine, and thebaine, are used in the pharmaceutical industry. Otherwise, Mallinckrodt denies the allegations.
- 132. No answer is required to Paragraph 132 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations. The fourth sentence of Paragraph 132 quotes from a *Washington Post* article. Mallinckrodt

respectfully refers the Court to this article for its complete content, which speaks for itself, and denies any inaccurate characterizations of the article or its meaning.

- 133. No answer is required to Paragraph 133 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations.
- 134. No answer is required to Paragraph 134 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations. Mallinckrodt objects to the terms "little difference" and "similar" as vague and undefined.
- 135. No answer is required to Paragraph 135 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations and objects to the term "usually" as vague and undefined.
- 136. No answer is required to Paragraph 136 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations and objects to the terms "generally" and "relatively low" as vague and undefined.
- 137. No answer is required to Paragraph 137 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations.
- 138. No answer is required to Paragraph 138 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations. Mallinckrodt objects to the terms "various," "one study," and "average" as vague and undefined.
- 139. No answer is required to Paragraph 139 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt admits that "Different opioids

provide varying levels of MMEs." Mallinckrodt denies Plaintiffs' characterization of "50 MME/day" as a "threshold." Otherwise, Mallinckrodt denies the allegations.

- 140. No answer is required to Paragraph 140 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations. Answering further, to the extent the term "manufacturers" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 140.
- 141. Paragraph 141 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 141. Mallinckrodt objects to the terms "100 times stronger," "50 times stronger," and "more and more often" as vague and undefined.
- 142. Paragraph 142 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 142. Mallinckrodt objects to the term "promoted" as vague and undefined.
- 143. No answer is required to Paragraph 143 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations in

- Paragraph 143. Mallinckrodt objects to the terms "relatively quickly," "typically," "very high," "often," "more severe," and "heightened" as vague and undefined.
- 144. No answer is required to Paragraph 144 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations. Mallinckrodt objects to the terms "most," "severe," and "serious" as vague and undefined. Mallinckrodt states that opioid medications carry certain well-known and disclosed risks, which are set forth in the FDA-approved warning labels for those medications.
- 145. No answer is required to Paragraph 145 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, denies the allegations and characterizations therefrom. Mallinckrodt objects to the characterization of the uncited quote from "one doctor."

E. The Resurgence of Opioid Use in the United States

1. The Sackler Family Integrated Advertising and Medicine

- 146. Paragraph 146 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 146.
- 147. No answer is required to Paragraph 147 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 148. No answer is required to Paragraph 148 as it asserts no allegations against Mallinckrodt. Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 148 and therefore denies the allegations.

- 149. No answer is required to Paragraph 149 as it asserts no allegations against Mallinckrodt. Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 149 and therefore denies the allegations.
- 150. No answer is required to Paragraph 150 as it asserts no allegations against Mallinckrodt. Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 150 and therefore denies the allegations.
- 151. Paragraph 151 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 151. Mallinckrodt objects to the terms "target" and "tailor" as vague and undefined.

2. Purdue and the Development of OxyContin

152-163. No answer is required to Paragraphs 152-163 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents and websites quoted in Paragraphs 152-163 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents and websites or their meaning.

3. Other Marketing Defendants Leapt at the Opioid Opportunity

164. Paragraph 164 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 164 and in the heading immediately preceding Paragraph 164.

165-169. No answer is required to Paragraphs 165-169 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

170. Paragraph 170 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 170.

F. Defendants' Conduct Created an Abatable Public Nuisance

- 171. Paragraph 171 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 171 and in the heading immediately preceding Paragraph 171.
- 172. Paragraph 172 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 172. Mallinckrodt states that

opioid medications carry certain well-known and disclosed risks, which are set forth in the FDAapproved warning labels for those medications.

173. Paragraph 173 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 173.

G. The Marketing Defendants' Multi-Pronged Scheme to Change Prescriber Habits and Public Perception and Increase Demand for Opioids

- 174. Paragraph 174 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 174 and in the heading immediately preceding Paragraph 174.
- 175. Paragraph 175 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 175. Mallinckrodt states that opioid medications carry certain well-known and disclosed risks, which are set forth in the FDA-approved warning labels for those medications. Mallinckrodt otherwise denies the allegations in Paragraph 175.
- 176. Paragraph 176 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 176.

1. The Marketing Defendants Promoted Multiple Falsehoods About Opioids

- 177. Paragraph 177 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 177 and in the heading immediately preceding Paragraph 177.
- 178. Paragraph 178 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 178.
- 179. Paragraph 179 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 179.

a. <u>Falsehood #1: The risk of addiction from chronic opioid</u> therapy is low

180. Paragraph 180 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 180 and in the heading immediately preceding Paragraph 180. Mallinckrodt objects to the terms "rarely," "low," and "advanced" as vague and undefined.

- 181. Paragraph 181 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 181. Mallinckrodt objects to the term "relatively small" as vague and undefined.
- 182. No answer is required to Paragraph 182 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations. Paragraph 182 quotes from and purports to characterize the CDC Guidelines. Mallinckrodt respectfully refers the Court to the CDC Guidelines mentioned in Paragraph 182 for their complete content, which speaks for itself, and denies any inaccurate characterizations of the CDC Guidelines or their meaning.

i. Purdue's misrepresentations regarding addiction risk

183. Paragraph 183 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 183 and in the heading immediately preceding Paragraph 183.

- 184. No answer is required to Paragraph 184 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 184 and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the document cited in Paragraph 184 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.
- 185. No answer is required to Paragraph 185 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 185 and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 185 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.
- 186. Paragraph 186 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 186. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 186 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.
- 187. No answer is required to Paragraph 187 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 187 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

188. Paragraph 188 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 188. Mallinckrodt respectfully refers the Court to the document quoted in Paragraph 188 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

189-202. No answer is required to Paragraphs 189-202 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents and websites quoted in Paragraphs 189-202 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents and websites or their meaning.

ii. Endo's misrepresentations regarding addiction risk

203-211. No answer is required to Paragraphs 203-211 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 203. Mallinckrodt respectfully refers the Court to the documents and websites cited in Paragraphs 203-211 for their complete content,

which speaks for itself, and denies any inaccurate characterizations of those documents and websites or their meaning.

iii. Janssen's misrepresentations regarding addiction risk

212-220. No answer is required to Paragraphs 212-220 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 212. Mallinckrodt respectfully refers the Court to the websites and documents cited in Paragraphs 212-220 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those websites and documents or their meaning.

iv. Cephalon's misrepresentations regarding addiction risk

221-223. No answer is required to Paragraphs 221-223 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 221. Mallinckrodt respectfully refers the Court to the websites and documents cited in Paragraphs 221-223 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those websites and documents or their meaning.

v. Actavis's misrepresentations regarding addiction risk

224-227. No answer is required to Paragraphs 224-227 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information

sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 224. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraphs 224-227 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those document or their meaning.

vi. Mallinckrodt's misrepresentations regarding addiction risk

- 228. Mallinckrodt denies the allegations in Paragraph 228 and in the heading immediately preceding Paragraph 228.
 - 229. Mallinckrodt admits the allegations in Paragraph 229.
- 230. Paragraph 230 quotes from and purports to characterize a book. Mallinckrodt respectfully refers the Court to the book for its complete content, which speaks for itself, and denies any inaccurate characterizations of the book or its meaning. Mallinckrodt denies the remaining allegations. Mallinckrodt denies that it was "promoting a book" as the term "promoting" is vague and undefined.
- 231. Paragraph 231 quotes from and purports to characterize a Mallinckrodt policy statement. Mallinckrodt respectfully refers the Court to the policy statement and report mentioned in Paragraph 231 for their complete content, which speaks for itself, and denies any inaccurate characterizations of that policy statement or report, or their meaning. Mallinckrodt otherwise denies remaining the allegations in Paragraph 231.
- 232. Paragraph 232 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 232. Mallinckrodt

also denies the characterization of patients who "doctor-shop" or otherwise unlawfully obtain opioids as a "small minority," expressed as a percentage or otherwise.

b. <u>Falsehood #2: To the extent there is a risk of addiction, it can</u> be easily identified and managed

233. Paragraph 233 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 233 and in the heading immediately preceding Paragraph 233.

234-239. No answer is required to Paragraphs 234-239 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents and websites mentioned in Paragraphs 234-239 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents and websites or their meaning.

240. Paragraph 240 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 240.

c. <u>Falsehood #3: Signs of addictive behavior are</u> "pseudoaddiction," requiring more opioids

- 241. Paragraph 241 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 241 and in the heading immediately preceding Paragraph 241. Mallinckrodt respectfully refers the Court to the study cited in Paragraph 241 for its complete content, which speaks for itself, and denies any inaccurate characterizations of the study or its meaning.
- 242. Paragraph 242 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 242.
- 243-251. No answer is required to Paragraphs 243-251 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents and websites mentioned in Paragraphs 243-251 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents and websites or their meaning.

d. Falsehood #4: Opioid withdrawal can be avoided by tapering

252. Paragraph 252 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or

information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 252 and in the heading immediately preceding Paragraph 252.

253-254. No answer is required to Paragraphs 253-254 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the programs mentioned in Paragraphs 253-254 for their complete content, which speaks for itself, and denies any inaccurate characterizations of the programs or their meaning.

255. Paragraph 255 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 255.

e. <u>Falsehood #5: Opioid doses can be increased without limit or greater risks</u>

256. Paragraph 256 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 256 and in the heading immediately preceding Paragraph 256. Mallinckrodt objects to the term "produced, sponsored or controlled" as vague and undefined.

- 257. Paragraph 257 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 257.
- 258-259. No answer is required to Paragraphs 258-259 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiff's allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents quoted in Paragraphs 258-259 for their complete content, and denies any inaccurate characterizations of those documents or their meanings.
- 260. No answer is required to Paragraph 260 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations. Mallinckrodt objects to the terms "particularly" and "just" as vague.
- 261-266. No answer is required to Paragraphs 261-266 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the websites and documents mentioned in Paragraphs 261-266 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meanings.
- 267. Paragraph 267 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or

information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 267. Mallinckrodt respectfully refers the Court to the data and studies mentioned in Paragraph 267 for their complete content, which speaks for itself, and denies any inaccurate characterizations of the data and studies or their meanings.

f. Falsehood #6: Long-term opioid use improves functioning

268. Paragraph 268 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations and in the heading immediately preceding Paragraph 268. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 268.

269-272. No answer is required to Paragraphs 269-272 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraphs 269-272 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.

273. No answer is required to Paragraph 273 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 273, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents mentioned in

Paragraph 273 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.

274-279. Paragraphs 274-279 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 274-279. Mallinckrodt respectfully refers the Court to the websites and documents mentioned or quoted in Paragraphs 274-279 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents and websites or their meaning.

- 280. Mallinckrodt respectfully refers the Court to the website cited in Paragraph 280 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that website or its meaning.
- 281. Paragraph 281 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 281. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraph 281 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.
- 282. No answer is required to Paragraph 282 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.

Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraph 282 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning. Mallinckrodt otherwise denies the allegations in Paragraph 282.

283-284. No answer is required to Paragraphs 283-284 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents and websites mentioned in Paragraphs 283-284 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents and websites or their meaning. Mallinckrodt otherwise denies the allegations in Paragraph 283-284.

g. <u>Falsehood #7: Alternative forms of pain relief pose greater risks than opioids</u>

285. Paragraph 285 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 285 and in the heading immediately preceding Paragraph 285.

286. Paragraph 286 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 286. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraph 286 for their

complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.

287-293. No answer is required to Paragraphs 287-293 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraphs 287-293. Mallinckrodt respectfully refers the Court to the websites and documents mentioned in Paragraphs 287-293 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those websites and documents or their meaning.

294. Paragraph 294 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 294. Mallinckrodt respectfully refers the Court to the study mentioned in Paragraph 294 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that study or its meaning.

h. Falsehood #8: OxyContin provides twelve hours of pain relief

295-298. No answer is required to Paragraphs 295-298 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

299. Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the

Court to the website mentioned in Paragraph 299 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that website or its meaning.

300-307. No answer is required to Paragraphs 300-307 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies those allegations.

i. <u>Falsehood #9: New formulations of certain opioids</u> successfully deter abuse

308. Paragraph 308 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 308. Mallinckrodt objects to the term "promoted" as vague and undefined.

309. Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents and reports mentioned in Paragraph 309 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents and reports or their meaning

i. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER

310-321. No answer is required to Paragraphs 310-321 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

ii. Endo's deceptive marketing of reformulated Opana ER

322-344. No answer is required to Paragraphs 322-344 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

iii. Other Marketing Defendants' misrepresentations regarding abuse deterrence

- 345. No answer is required to Paragraph 345 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 346. Mallinckrodt denies the allegations. Mallinckrodt respectfully refers the Court to the documents cited in Paragraph 346 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.
- 347. Mallinckrodt denies the allegations in Paragraph 347. Mallinckrodt respectfully refers the Court to the website cited in Paragraph 347 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning. Mallinckrodt specifically denies Plaintiffs' characterization of the cited *Responsible Use of Opioid Medications* slide deck as "promotional material."
- 348-349. Paragraphs 348-349 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 348-349.

2. The Marketing Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels

350-351. Paragraphs 350-351 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 350-351 and in the heading immediately preceding Paragraph 350.

a. The Marketing Defendants Directed Front Groups to Deceptively Promote Opioid Use

- 352. Paragraph 352 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 352.
- 353-354. Paragraphs 353-354 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 353-354. Mallinckrodt respectfully refers the Court to the studies mentioned in Paragraphs 353-354 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those studies or their meaning.
- 355. Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the

Court to the report mentioned in Paragraph 355 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that report or its meaning.

356. Paragraph 356 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 356.

i. American Pain Foundation

357-360. No answer is required to Paragraphs 357-360 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents and websites mentioned in Paragraphs 357-360 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents and websites or their meaning.

- 361. Paragraph 361 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 361.
- 362. No answer is required to Paragraph 362 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

Mallinckrodt respectfully refers the Court to the document quoted in Paragraph 362 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

- 363. Paragraph 363 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" or "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 363.
- 364. Paragraph 364 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 364.

ii. American Academy of Pain Medicine and the American Pain Society

365. No answer is required to Paragraph 365 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the website cited in Paragraph 365 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that website or its meaning. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 365. Mallinckrodt objects to the term "substantial funding" as vague and undefined.

- 366. No answer is required to Paragraph 366 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. To the extent "opioid manufacturers" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 366.
- 367. Paragraph 367 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 367. Mallinckrodt respectfully refers the Court to the interview mentioned in Paragraph 367 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that interview or its meaning.
- 368. No answer is required to Paragraph 368 as it asserts no allegations against Mallinckrodt. Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- 369. No answer is required to Paragraph 369 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 370. Paragraph 370 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than

Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 370.

- 371. Paragraph 371 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 371.
- 372. No answer is required to Paragraph 372 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- 373. No answer is required to Paragraph 373 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- 374. Paragraph 374 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 374. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 374 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

- 375. No answer is required to Paragraph 375 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- 376. Paragraph 376 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 376.

iii. Federation of State Medical Boards

- 377. No answer is required to Paragraph 377 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- 378. Paragraph 378 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 378. Mallinckrodt objects to the term "finances" as vague and undefined.
- 379-380. No answer is required to Paragraphs 379-380 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraphs 379-380 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents, or their meaning.

- 381. No answer is required to Paragraph 381 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the publication cited in Paragraph 381 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that publication or its meaning.
- 382. Paragraph 382 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 382. Mallinckrodt respectfully refers the Court to the guidelines mentioned in Paragraph 382 for its complete content, which speaks for itself, and denies any inaccurate characterizations of those guidelines or their meaning.

iv. The Alliance for Patient Access

383. Paragraph 383 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. Mallinckrodt admits that as of June 2017, it was an Associate Member and Financial Supporter of APA. Mallinckrodt respectfully refers the Court to the documents cited in Paragraph 383 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents, or their meaning. Mallinckrodt denies the remaining allegations in Paragraph 383.

384. Paragraph 384 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. With respect to the fourth sentence, Mallinckrodt denies the allegations in Paragraph 384. Mallinckrodt objects to the terms "including," "more than \$240,000," and "from pharmaceutical companies" as vague.

385-389. No answer is required to Paragraphs 385-389 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraphs 385-389 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.

390. No answer is required to Paragraph 390 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the Controlled Substances Act ("CSA"), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize them.

v. The U.S. Pain Foundation

391. Paragraph 391 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants"

pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 391. Mallinckrodt respectfully refers the Court to the website mentioned in Paragraph 391 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that website or its meaning. Mallinckrodt objects to the characterization of Mallinckrodt as a "'Platinum,' 'Gold,' and 'Basic' corporate member."

vi. American Geriatrics Society

392. Paragraph 392 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 392. Mallinckrodt respectfully refers the Court to the guidelines mentioned in Paragraph 392 for its complete content, which speaks for itself, and denies any inaccurate characterizations of those guidelines or their meaning.

393. No answer is required to Paragraph 393 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the guidelines mentioned in Paragraph 393 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those guidelines or their meaning.

394-395. Paragraphs 394-395 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than

Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 394-395.

b. The Marketing Defendants Paid Key Opinion Leaders to Deceptively Promote Opioid Use

396-403. Paragraphs 396-403 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 396-403 and in the heading immediately preceding Paragraph 396.

i. Dr. Russell Portenoy

404-405. No answer is required to Paragraphs 404-405 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraphs 404-405 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.

406. Paragraph 406 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 406. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 406 for its complete content, which speaks for itself, and denies any inaccurate characterizations of the document or its meaning.

- 407. No answer is required to Paragraph 407 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the document cited in Paragraph 407 for their complete content, which speaks for itself, and denies any inaccurate characterizations of the document or its meaning.
- 408. Paragraph 408 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 408.
- 409. Paragraph 409 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 409. Mallinckrodt respectfully refers the Court to the article mentioned in Paragraph 409 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that article or its meaning.
- 410-411. No answer is required to Paragraphs 410-411 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the websites mentioned in Paragraphs

410-411 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those websites or their meaning.

ii. Dr. Lynn Webster

- 412. No answer is required to Paragraph 412 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties and entities, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 412.
- 413. No answer is required to Paragraph 413 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 413.
- 414. Paragraph 414 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 414.
- 415-416. No answer is required to Paragraphs 415-416 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

iii. Dr. Perry Fine

417. Paragraph 417 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 417.

418-423. No answer is required to Paragraphs 418-423 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents and websites mentioned in Paragraphs 418-423 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents and websites or their meaning.

iv. Dr. Scott Fishman

424. Paragraph 424 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 424. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 424 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning

425-428. No answer is required to Paragraphs 425-428 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the

allegations. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraphs 425-428 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.

c. The Marketing Defendants Disseminated Their Misrepresentations Through Continuing Medical Education Programs

- 429. Paragraph 429 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 429 and in the heading immediately preceding Paragraph 429.
- 430. Paragraph 430 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 430.
- 431. No answer is required to Paragraph 431 as it asserts no allegations against Mallinckrodt. Mallinckrodt admits that a Continuing Medical Education course is an educational program for doctors. To the extent further answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations.
- 432-433. Paragraphs 432-433 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than

Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 432-433.

434. No answer is required to Paragraph 434 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraph 434.

435-439. No answer is required to Paragraphs 435-439 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraphs 435-439 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.

440-441. Paragraphs 440-441 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 440-441.

d. The Marketing Defendants Used "Branded" Advertising to Promote their Products to Doctors and Consumers

442. Paragraph 442 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than

Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 442 and in the heading immediately preceding Paragraph 442. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 442 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

443. Paragraph 443 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 443.

e. The Marketing Defendants Used "Unbranded" Advertising to Promote Opioid Use for Chronic Pain Without FDA Review

- 444. Paragraph 444 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 444 and in the heading immediately preceding Paragraph 444.
- 445. Paragraph 445 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 445. Mallinckrodt respectfully refers the Court to the website mentioned in Paragraph 445 for its complete content,

which speaks for itself, and denies any inaccurate characterizations of that website or its meaning.

f. The Marketing Defendants Funded, Edited and Distributed Publications That Supported Their Misrepresentations

446. Paragraph 446 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 446.

447-450. Paragraphs 447-450 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 447-450.

451. No answer is required to Paragraph 451 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

g. The Marketing Defendants Used Detailing to Directly Disseminate Their Misrepresentations to Prescribers

452. Paragraph 452 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants"

pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 452 and in the heading immediately preceding Paragraph 452.

- 453. Paragraph 453 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 453. Mallinckrodt objects to the terms "promote" and "promoted" as vague and undefined.
- 454. Paragraph 454 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt states that it utilized data from IMS Health to evaluate information relating to estimated market share for certain products. Mallinckrodt otherwise denies the allegations in Paragraph 454. Mallinckrodt objects to the terms "common industry practice," "track," "target," and "tailor" as vague and undefined.
- 455. Paragraph 455 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 455.
- 456-461. No answer is required to Paragraphs 456-461 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to

Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

h. <u>Marketing Defendants Used Speakers' Bureaus and</u> Programs to Spread Their Deceptive Messages

462. Paragraph 462 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketers" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt admits that it contracted with certain doctors to serve as speakers or to provide consulting services and that it lawfully made certain payments in connection with these services. Mallinckrodt otherwise denies the allegations in Paragraph 462 and in the heading immediately preceding Paragraph 462. Mallinckrodt further denies the allegations in the fourth sentence. Mallinckrodt objects to the term "thousands of payments" as vague and undefined.

463-464. No answer is required to Paragraphs 463-464 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

3. The Marketing Defendants Targeted Vulnerable Populations

465. Paragraph 465 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 465 and in the heading immediately preceding Paragraph 465.

- 466. No answer is required to Paragraph 466 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt denies the allegations. Mallinckrodt objects to the overgeneralizations and to the terms "greater," "increased," and "more frequently" as vague and undefined.
- 467. Paragraph 467 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 467. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 467 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.
- 468. No answer is required to Paragraph 468 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraph 468.
- 469. No answer is required to Paragraph 469 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations in Paragraph 469.
- 470. Paragraph 470 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than

Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 470. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 470 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

471. No answer is required to Paragraph 471 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations in Paragraph 471.

4. <u>Insys Employed Fraudulent, Illegal, and Misleading Marketing</u> <u>Schemes to Promote Subsys</u>

472-486. No answer is required to Paragraphs 472-486 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 472.

5. <u>The Marketing Defendants' Scheme Succeeded, Creating a Public</u> Health Epidemic.

a. <u>Marketing Defendants Dramatically Expanded Opioid</u> Prescribing and Use

487. Paragraph 487 was deleted and therefore no answer is required. To the extent an answer is required, Paragraph 487 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants"

pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 487 and in the two headings immediately preceding Paragraph 487.

488. Paragraph 488 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 488.

489-490. No answer is required to Paragraphs 489-490 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraphs 489-490.

- 491. Paragraph 491 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 491.
- 492. No answer is required to Paragraph 492 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations in Paragraph 492.
- 493. Paragraph 493 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than

Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 493.

494. Paragraph 494 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 494.

1. <u>Marketing Defendants' Deception in Expanding Their Market Created and Fueled the Opioid Epidemic</u>

- 495. No answer is required to Paragraph 495 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt respectfully refers the Court to the study mentioned in Paragraph 495 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that study or its meaning. Mallinckrodt denies the remaining allegations in Paragraph 495 and in the heading immediately preceding Paragraph 495.
- 496. No answer is required to Paragraph 496 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt respectfully refers the Court to the study mentioned in Paragraph 496 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that study or its meaning. Mallinckrodt denies the remaining allegations.
- 497. Paragraph 497 was deleted and therefore no answer is required. To the extent an answer is required, no answer is required to Paragraph 497 as it asserts no allegations against Mallinckrodt. Paragraph 497 quotes from and purports to characterize the CDC Guidelines. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 497 for its

complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning. Mallinckrodt denies the remaining allegations.

E. <u>Defendants Throughout the Supply Chain Deliberately Disregarded Their Duties to Maintain Effective Controls and to Identify, Report, and Take Steps to Halt Suspicious Orders</u>

498-499. Paragraphs 498-499 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 498-499 and in the heading immediately preceding Paragraphs 498-499.

500. Paragraph 500 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 500. Mallinckrodt respectfully refers the Court to 21 U.S.C. § 823 and 21 C.F.R. §§ 1301.11, and 1301.74., which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes. Mallinckrodt objects to the term "either" as vague.

1. All Defendants Have a Duty to Report Suspicious Orders and Not to Ship Those Orders Unless Due Diligence Disproves Their Suspicions

501-505. Paragraphs 501-505 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 501-

505 and in the heading immediately preceding Paragraph 501. Mallinckrodt respectfully refers the Court to 21 U.S.C. § 823, 21 C.F.R. §§ 0.100, and 1301.74, and applicable state laws, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize them.

506-511. Paragraphs 506-511 asserts legal conclusions to which no answer is required. To the extent a response is required, Mallinckrodt respectfully refers the Court to the Controlled Substances Act ("CSA"), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

512-514. Paragraphs 512-514 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 512-514. Mallinckrodt objects to the terms "state and federal law," "enforcement authorities," "statue and federal statutes and regulations," and "industry guidelines" as vague and undefined.

- 515. No answer is required to Paragraph 515 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 516. Paragraph 516 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing

Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 516. Mallinckrodt denies Plaintiffs' characterization of "chargeback data" as necessarily "allow[ing] [Marketing Defendants] to monitor the combined flow of opioids into a pharmacy or geographic area and/or detailed information about prescribing habits[.]" Mallinckrodt respectfully refers the Court to the CSA, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

- 517. Paragraph 517 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 517.
- 518. Paragraph 518 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 518.
 - 2. <u>Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders</u>
- 519. No answer is required to Paragraph 519 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 519.
- 520. Paragraph 520 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 520.

- 521. Paragraph 521 quotes from and purports to characterize Mallinckrodt's July 2017 civil settlement with DEA ("DEA settlement"). Mallinckrodt respectfully refers the Court to the DEA settlement for its complete content, which speaks for itself, and denies any inaccurate characterizations of the settlement or its meaning. Mallinckrodt denies the remaining allegations in Paragraph 521.
- 522-524. Paragraphs 522-524 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 522-524. Mallinckrodt respectfully refers the Court to the documents mentioned in Paragraphs 522-524 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meanings.
- 525. Paragraph 525 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 525. Mallinckrodt respectfully refers the Court to the letter mentioned in Paragraph 525 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that letter or its meaning.

3. <u>Defendants Worked Together to Inflate the Quotas of Opioids They Could Distribute</u>

- 526. Paragraph 526 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 526 and in the heading immediately preceding Paragraph 526.
- 527. Paragraph 527 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 527.
- 528. Paragraph 528 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 528.
- 529. The first sentence of Paragraph 529 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. The second sentence of Paragraph 529 merely quotes from and purports to characterize a *Washington Post* article. Mallinckrodt respectfully refers the Court to this article for its complete content and denies any inaccurate characterizations of the article or its meaning. The third sentence of Paragraph 529 quotes from and purports to characterize the DEA settlement. Mallinckrodt respectfully refers the Court to

the DEA settlement for its complete content, which speaks for itself, and denies any inaccurate characterizations of the settlement or its meaning. In particular, Mallinckrodt denies Plaintiffs' characterization of "chargeback data" as necessarily "revealing suspicious orders[.]" To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 529.

- 530. Paragraph 530 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 530. Mallinckrodt objects to the terms "vault security programs," "security protocols," "security vaults," and "required sales requirements" as vague and undefined.
- 531. Paragraph 531 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 531.
- 532. No answer is required to Paragraph 532 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 532 and therefore denies the allegations.
- 533. No answer is required to Paragraph 533 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 533 and therefore

denies the allegations. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 533 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

- 534. Paragraph 534 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations in Paragraph 534. With respect to footnote 151, Mallinckrodt states that it was a member of the Pain Care Forum. Mallinckrodt denies the remaining allegations in Paragraph 534 and footnote 151.
- 535. Paragraph 535 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 535. Mallinckrodt respectfully refers the Court to the websites quoted in Paragraph 535 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those websites or their meaning. Mallinckrodt states that it has been a member of the Healthcare Distribution Alliance. Mallinckrodt denies the remaining allegations in Paragraph 535.

536-538. Paragraphs 536-538 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 536-538. Mallinckrodt respectfully refers the Court to the website quoted in Paragraphs 536-538 for its complete

content, which speaks for itself, and denies any inaccurate characterizations of that website or its meaning.

539. Paragraph 539 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 539.

540-542. Paragraphs 540-542 assert allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the website quoted in Paragraphs 540-542 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that website or its meaning. To the extent "Marketing Defendants" or "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 540-542.

- 543. Paragraph 543 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" or "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 543.
- 544. Paragraph 544 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 544.

- 545. Paragraph 545 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 545. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 545 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.
- 546. Paragraph 546 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 546. Mallinckrodt respectfully refers the Court to the speech quoted in Paragraph 546 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that speech or its meaning.
- 547. Paragraph 547 was deleted and therefore no answer is required. To the extent an answer is required, Paragraph 547 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 547.
- 548-553. Paragraphs 548-553 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing

Defendants" or "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 548-553.

1. <u>Defendants Kept Careful Track of Prescribing</u> <u>Data and Knew About Suspicious Orders and</u> <u>Prescribers</u>

- 554. Paragraph 554 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 554 and in the heading immediately preceding Paragraph 554.
- 555. Paragraph 555 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 555.
- 556. Paragraph 556 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 556. Mallinckrodt objects to the terms "access," "make use," "monitor," and "combined flow" as vague and undefined.
- 557. Paragraph 557 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or

information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 557.

- 558. Paragraph 558 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 558. Mallinckrodt objects to the terms "data," "prescribing patterns," and "information" as vague and undefined. Mallinckrodt states that it received data from IMS Health and Wolters Kluwer.
- 559. No answer is required to Paragraph 559 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs 'allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies those allegations. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 559 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.
- 560. Paragraph 560 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 560. Mallinckrodt objects to the terms "data," "prescribing trends," and "information" as vague and undefined. Mallinckrodt

states that it utilized data from IMS Health to evaluate information relating to estimated market share for certain products.

- 561. Paragraph 561 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 561. Mallinckrodt objects to the term "prescriber behavior" as vague and undefined.
- 562. Paragraph 562 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 562. Mallinckrodt objects to the term "prescribing patterns" as vague and undefined.
- 563. Paragraph 563 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 563. The second sentence of Paragraph 563 refers to and purports to characterize the testimony of Eugene "Mick" Kolassa. Mallinckrodt respectfully refers the Court to the testimony for its complete content, which speaks for itself, and denies any inaccurate characterizations of the testimony or its meaning.
- 564. Paragraph 564 was deleted and therefore no answer is required. To the extent an answer is required, no answer is required because Paragraph 564 asserts no allegations against

Mallinckrodt. To the extent further answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

- 565. Paragraph 565 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 565.
- 566. Paragraph 566 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 566.
- 567. No answer is required to Paragraph 567 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraph 567.
- 568. Paragraph 568 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 568.
- 569. No answer is required to Paragraph 569 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs'

allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraph 569.

- 570. Paragraph 570 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 570.
- 571. Paragraph 571 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 571. Mallinckrodt objects to the terms "other proprietary sources" and "marketing visits" as vague and undefined. Mallinckrodt states that it utilized data from IMS Health to evaluate information relating to estimated market share for certain products.
- 572. No answer is required to Paragraph 572 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 573. Paragraph 573 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than

Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 573.

- 574. Paragraph 574 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 574.
- 575. Paragraph 575 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 575. Mallinckrodt respectfully refers the Court to testimony quoted in Paragraph 575 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that testimony or its meaning.
- 576. Paragraph 576 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 576.
- 577. No answer is required to Paragraph 577 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

578. Paragraph 578 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 578.

2. <u>Defendants Failed to Report Suspicious Orders</u> or Otherwise Act to Prevent Diversion

- 579. Paragraph 579 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 579 and in the heading immediately preceding Paragraph 579.
- 580. Paragraph 580 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 580.
- 581-582. No answer is required to Paragraphs 581-582 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 583. Paragraph 583 quotes from and purports to characterize the DEA settlement with Mallinckrodt. Mallinckrodt respectfully refers the Court to the DEA settlement for its complete

content, which speaks for itself, and denies any inaccurate characterizations of the settlement or its meaning. Mallinckrodt denies the remaining allegations in Paragraph 583.

584-592. No answer is required to Paragraphs 584-592 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraphs 584-592.

593. Paragraph 593 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 593.

3. <u>Defendants Delayed an Answer to the Opioid</u> <u>Crisis by Pretending to Cooperate with Law</u> <u>Enforcement</u>

594. No answer is required to Paragraph 594 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 594 and therefore denies the allegations and in the heading immediately preceding Paragraph 594.

595-598. No answer is required to Paragraphs 595-598 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

599-600. Paragraphs 599-600 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks

sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 599-600. Mallinckrodt respectfully refers the Court to document quoted in Paragraphs 599-600 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

- 601. Paragraph 601 quotes from and purports to characterize Mallinckrodt's opioid policy statement.² Mallinckrodt respectfully refers the Court to the policy statement for its complete content, which speaks for itself, and denies any inaccurate characterizations of the settlement or its meaning. Mallinckrodt denies the remaining allegations in Paragraph 601.
- 602. Paragraph 602 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 602.

603-605. No answer is required to Paragraphs 603-605 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

606. Paragraph 606 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

² The policy statement no longer appears on Mallinckrodt's website but can be found at https://web.archive.org/web/20140701095355/http://mallinckrodt.com/Responsibility/Responsible Use/Our Programs/

other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 606.

4. The National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids

607-610. No answer is required to Paragraphs 607-610 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraphs 607-610 and in the heading immediately preceding Paragraph 607.

a. The National Retail Pharmacies Have a Duty to Prevent Diversion

611-626. No answer is required to Paragraphs 611-626 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 611. Mallinckrodt respectfully refers the Court to the statutes listed in Paragraphs 611-626, which speak for themselves, and denies any inaccurate characterizations of the statutes or their meaning.

b. <u>Multiple Enforcement Actions against the National Retail Pharmacies Confirms their Compliance Failures</u>

627. No answer is required to Paragraph 627 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 627.

i. CVS

628-640. No answer is required to Paragraphs 628-640 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

ii. Walgreens

641-649. No answer is required to Paragraphs 641-649 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

iii. Rite Aid

650-659. No answer is required to Paragraphs 650-659 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

F. The Opioids the Defendants Sold Migrated into Other Jurisdictions

660-670. No answer is required to Paragraphs 660-670 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraphs 660-670 and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the documents listed in Paragraphs 660-670 for their complete content, which speaks for itself, and denies any inaccurate characterizations of the documents or their meaning.

G. Ohio-Specific Facts

671. Paragraph 671 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 671.

1. The Devastating Effects of the Opioid Crisis in Ohio and Plaintiffs' Communities

a. <u>Marketing Defendants' Implementation of Their Scheme in Summit County</u>

- 672. Paragraph 672 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 672 and the two headings immediately preceding Paragraph 672.
- 673. Paragraph 673 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. Mallinckrodt admits Mallinckrodt sales representatives visited Summit County. Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the remaining allegations in the second, third, and fourth sentences of Paragraph 673 and therefore denies the allegations.
- 674. Paragraph 674 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or

information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. Mallinckrodt admits that certain of its opioid drugs have been prescribed in Summit County. Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the remaining allegations in the first, third, fourth, and fifth sentences of Paragraph 674 and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 674.

- 675. No answer is required to Paragraph 675 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 676. Paragraph 676 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 676.
- 677. No answer is required to Paragraph 677 as it asserts no legal conclusions or allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 678. Paragraph 678 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 678.

679-680. No answer is required to Paragraphs 679-680 as they assert no legal conclusions or allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraphs 679-680.

681. No answer is required to Paragraph 681 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 681 and therefore denies the allegations.

682-683. No answer is required to Paragraphs 682-683 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

b. Defendants Breached Their Duties in Ohio

684-685. No answer is required to Paragraphs 684-685 as they assert no legal conclusions or allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 684. Mallinckrodt respectfully refers the Court to the statutes listed in Paragraphs 684-685, which speak for themselves, and denies any inaccurate characterizations of the statutes or their meaning.

- 686. Paragraph 686 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 686.
- 687. No answer is required to Paragraph 687 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraph 687.
- 688. Paragraph 688 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 688.
- 689. No answer is required to Paragraph 689 as it asserts no legal conclusions or allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 689 and therefore denies the allegations.
- 690. No answer is required to Paragraph 690 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 690 and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the data mentioned in Paragraph 690 for its complete content, which speaks for itself, and denies any inaccurate characterizations of the data or its meaning.

- 691. No answer is required to Paragraph 691 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 691 and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the data mentioned in Paragraph 691 for its complete content, which speaks for itself, and denies any inaccurate characterizations of the data or its meaning.
- 692. No answer is required to Paragraph 692 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 692 and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the data mentioned in Paragraph 692 for its complete content, which speaks for itself, and denies any inaccurate characterizations of the data or its meaning.
- 693-696. No answer is required to Paragraphs 693-696 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 697-700. No answer is required to Paragraphs 697-700 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraphs 697-700 and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the data cited in Paragraphs 697-700 for its complete content, which speaks for itself, and denies any inaccurate characterizations of the data or its meaning.
- 701. Paragraph 701 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or

information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 701.

702. Paragraph 702 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. Subparagraphs (f) and (g) refer to and purport to characterize the DEA settlement. Mallinckrodt respectfully refers the Court to the DEA settlement for its complete content, which speaks for itself, and denies any inaccurate characterizations of the settlement or its meaning. Mallinckrodt denies the remaining allegations in Paragraph 702. Mallinckrodt objects to the term "systematic failures" and denies Plaintiffs' characterization of "chargeback data" as necessarily "allow[ing] [Manufacturers] to monitor the combined flow of opioids into a pharmacy or geographic area and/or detailed information about prescribing habits[.]"

703-704. Paragraphs 703-704 were deleted and therefore no answer is required. To the extent an answer is required, no answer is required to Paragraphs 703-704 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

705. Paragraph 705 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than

Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 705.

706-707. No answer is required to Paragraphs 706-707 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations in Paragraphs 706-707. Mallinckrodt respectfully refers the Court to the website quoted in Paragraphs 706-707 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that website or its meaning.

708. Paragraph 708 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 708.

- 709. Paragraph 709 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 709.
- 710. Paragraph 710 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 710.

- 711. Paragraph 711 was deleted and therefore no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 711 and therefore denies the allegations.
- 712. Paragraph 712 quotes and purports to characterize a *Washington Post* article and the Declaration of DEA Diversion Investigator Christopher Kresnak. Mallinckrodt respectfully refers the Court to the article and Declaration for their complete content, which speaks for itself, and denies any inaccurate characterizations of the article and Declaration or their meanings. Mallinckrodt denies the remaining allegations in Paragraph 712.
- 713. Paragraph 713 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 713.
 - c. By Dramatically Increasing Prescription Opioid
 Prescribing and Use, Defendants Have Created a
 Public Health Crisis in Summit County
- 714. Paragraph 714 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 714 and in the heading immediately preceding Paragraph 714.
- 715-745. No answer is required to Paragraphs 715-745 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the

allegations in Paragraphs 715-745. Mallinckrodt respectfully refers the Court to the statistics and documents mentioned in Paragraphs 715-745 for their complete content, which speaks for itself, and denies any inaccurate characterizations of the statistics or the documents or their meaning.

H. <u>The Defendants Conspired To Engage In The Wrongful Conduct Complained Of Herein and Intended To Benefit Both Independently and Jointly From Their Conspiracy</u>

1. Conspiracy Among Marketing Defendants

- 746. Paragraph 746 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 746 and the two headings immediately preceding Paragraph 746.
- 747. Paragraph 747 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 747.
- 748. Paragraph 748 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 748.
- 749. Paragraph 749 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 749.

- 750. Paragraph 750 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 750.
- 751. Paragraph 751 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 751.
- 752. Paragraph 752 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 752.
- 753. Paragraph 753 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph753.

- 754. Paragraph 754 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 754.
- 755. Paragraph 755 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 755.
- 756. Paragraph 756 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 756. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 756 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.
- 757. Paragraph 757 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 757. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 757 for its complete

content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

- 758. Paragraph 758 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" or "opioid manufacturers" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 758. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 758 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.
- 759. Paragraph 759 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 759.

2. Conspiracy Among All Defendants

- 760. Paragraph 760 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 760.
- 761. Paragraph 761 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 761.

- 762. Paragraph 762 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 762.
- 763. Paragraphs 763-766 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 763-766.

I. <u>Statutes Of Limitations Are Tolled and Defendants Are Estopped From Asserting Statutes Of Limitations As Defenses</u>

1. Continuing Conduct

767. Paragraph 767 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 767 and the two headings immediately preceding Paragraph 767.

768. Paragraph 768 asserts legal conclusions and relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

2. Equitable Estoppel and Fraudulent Concealment

- 769. Paragraph 769 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 769.
- 770. Paragraph 770 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 770.
- 771. Paragraph 771 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 771.
- 772. Paragraph 772 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 772.

- 773. Paragraph 773 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 773.
- 774. Paragraph 774 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 774.

775-777. Paragraphs 775-777 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 775-777. Mallinckrodt respectfully refers the Court to its Order mentioned in Paragraphs 775-777 for its complete content, which speaks for itself, and denies any inaccurate characterizations of the data or its meaning.

J. Facts Pertaining to Punitive Damages

778. Paragraph 778 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or

"Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 778 and in the heading immediately preceding Paragraph 778.

779-781. Paragraphs 779-781 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 779-781.

1. <u>The Marketing Defendants Persisted in Their Fraudulent Scheme</u> Despite Repeated Admonitions, Warnings, and Even Prosecutions

782. Paragraph 782 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 782 and in the heading immediately preceding Paragraph 782.

a. FDA Warnings to Janssen Failed to Deter Janssen's Misleading Promotion of Duragesic

783-785. No answer is required to Paragraphs 783-785 of as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 783.

b. Governmental Action, Including Large Monetary Fines, Failed to Stop Cephalon from Falsely Marketing Actiq for Off-Label Uses

786-787. No answer is required to Paragraphs 786-787 of as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 786.

c. <u>FDA Warnings Did Not Prevent Cephalon from</u> Continuing False and Off-Label Marketing of Fentora

788-790. No answer is required to Paragraphs 788-790 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 788.

d. A Guilty Plea and a Large Fine Did Not Deter Purdue from Continuing Its Fraudulent Marketing of OxyContin

791-792. No answer is required to Paragraphs 791-792 as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations and in the heading immediately preceding Paragraph 791.

2. Repeated Admonishments and Fines Did Not Stop Defendants from Ignoring Their Obligations to Control the Supply Chain and Prevent Diversion

793. Paragraph 793 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 793 and in the heading immediately preceding Paragraph 793.

794. Paragraph 794 asserts allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 794. Mallinckrodt respectfully refers the Court to the *60 Minutes* interview quoted in Paragraph 794 for its complete content, which speaks for itself, and denies any inaccurate characterizations of the interview or its meaning.

795. No answer is required to Paragraph 795 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 795 and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the *60 Minutes* interview and statement quoted in Paragraph 795 for its complete content, which speaks for itself, and denies any inaccurate characterizations of the interview or the statement or their meaning.

796-812. No answer is required to Paragraphs 796-812³ as they assert no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.

³ Paragraphs 805-807 have been deleted from the Complaint and therefore no response is required.

813. Paragraph 813 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 813.

II. <u>FACTS PERTAINING TO CLAIMS UNDER RACKETEER-INFLUENCED AND</u> CORRUPT ORGANIZATIONS ("RICO") ACT

A. The Opioid Marketing Enterprise

- 1. <u>The Common Purpose and Scheme of the Opioid Marketing Enterprise</u>
- 814. Paragraph 814 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 814 and in the heading immediately preceding Paragraph 814.
- 815. Paragraph 815 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 815.
- 816. Paragraph 816 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 816.

- 817. Paragraph 817 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 817.
- 818. Paragraph 818 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 818.
- 819. Paragraph 819 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 819.
- 820. Paragraph 820 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 820.
- 821. Paragraph 821 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 821.

- 822. Paragraph 822 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 822.
- 823. Paragraph 823 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 823. Mallinckrodt respectfully refers the Court to the document mentioned in Paragraph 823 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.
- 824. No answer is required to Paragraph 824 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 824 and therefore denies the allegations.
- 825. No answer is required to Paragraph 825 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations in Paragraph 825 and therefore denies the allegations.

- 826. Paragraph 826 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 826.
- 827. Paragraph 827 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 827.
- 828. Paragraph 828 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 828.

2. The Conduct of the Opioid Marketing Enterprise violated Civil RICO

829. Paragraph 829 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 829 and in the heading immediately preceding Paragraph 829.

- 830. Paragraph 830 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 830.
- 831. Paragraph 831 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 831.
- 832. Paragraph 832 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 832. Mallinckrodt respectfully refers the Court to the documents quoted in Paragraph 832 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning.
- 833. Paragraph 833 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing"

Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 833.

834. Paragraph 834 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 834.

3. The RICO Marketing Defendants Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use

- 835. Paragraph 835 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 835 and the heading immediately preceding Paragraph 835.
- 836. Paragraph 836 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 836.
- 837. Paragraph 837 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing"

Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 837.

4. Pattern of Racketeering Activity

- 838. Paragraph 838 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 838 and in the heading immediately preceding Paragraph 838.
- 839. Paragraph 839 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 839.
- 840. Paragraph 840 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 840.
- 841. Paragraph 841 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing"

Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 841.

- 842. Paragraph 842 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 842.
- 843. Paragraph 843 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 843.
- 844. Paragraph 844 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 844.
- 845. Paragraph 845 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 845.

- 846. Paragraph 846 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 846.
- 847. Paragraph 847 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 847.
- 848. Paragraph 848 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 848.

B. The Opioid Supply Chain Enterprise

849. Paragraph 849 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 849. Mallinckrodt respectfully refers the Court to the document quoted in

Paragraph 849 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

- 850. Paragraph 850 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 850. Mallinckrodt respectfully refers the Court to the CSA, which speaks for itself, and denies any inaccurate characterizations of the CSA or its meaning.
- 851. Paragraph 851 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 851. Mallinckrodt respectfully refers the Court to 21 C.F.R. § 1301.74(b), which speaks for itself, and denies any inaccurate characterizations of the 21 C.F.R. § 1301.74(b) or its meaning.
- 852. Paragraph 852 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 852. Mallinckrodt respectfully refers the Court to the CSA and RICO statute mentioned in Paragraph

852, which speak for themselves, and denies any inaccurate characterizations of the CSA and RICO statute or their meaning.

- 853. Paragraph 853 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 853. Mallinckrodt respectfully refers the Court to the Guidelines and testimony mentioned in Paragraph 853 for their complete content, which speaks for itself, and denies any inaccurate characterizations of the Guidelines and testimony or their meaning.
- 854. Paragraph 854 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 854.
- 855. Paragraph 855 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 855. Mallinckrodt respectfully refers the Court to the CSA, which speaks for itself, and denies any inaccurate characterizations of the CSA or its meaning.
- 856. Paragraph 856 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 856.

- 857. Paragraph 857 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 857. Mallinckrodt respectfully refers the Court to the documents cited in Paragraph 857 for their complete content, which speaks for itself, and denies any inaccurate characterizations of those documents or their meaning
- 858. Paragraph 858 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 858. Mallinckrodt respectfully refers the Court to the CSA and Code of Federal Regulations mentioned in Paragraph 858 for their complete content, which speak for themselves, and denies any inaccurate characterizations of the CSA and Code of Federal Regulations or their meaning.
- 859. Paragraph 859 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 859.

- 860. Paragraph 860 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 860.
- 861. Paragraph 861 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 861.
- 862. Paragraph 862 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 862.
- 863. Paragraph 863 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 863. Mallinckrodt respectfully refers the Court to 21 U.S.C. § 827, 21 U.S.C. § 823, 21 C.F.R. § 1301.74, which speak for themselves, and denies any inaccurate characterizations of those statutes and regulations or their meaning.

- 864. Paragraph 864 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 864.
- 865. Paragraph 865 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 865.
- 866. Paragraph 866 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 866.
- 867. Paragraph 867 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 867.
- 868. Paragraph 868 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain

Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 868. Mallinckrodt objects to the term "information" as vague and undefined.

- 869. Paragraph 869 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 869.
- 870. Paragraph 870 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 870.
- 871. Paragraph 871 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 871.
- 872. Paragraph 872 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 872.

- 873. Paragraph 873 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations and therefore denies the allegations.
- 874. Paragraph 874 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 874.
- 875. Paragraph 875 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 875. Mallinckrodt respectfully refers the Court to 21 C.F.R. § 1301.74, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 876. Paragraph 876 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 876.
- 877. Paragraph 877 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 877.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 et seq. — Opioid Marketing Enterprise (Against Purdue, Cephalon, Janssen, Endo, and Mallinckrodt (the "RICO Marketing Defendants"))

- 878. Mallinckrodt incorporates by reference its answers to all other paragraphs with the same legal force and effect as if fully set forth at length herein.
- 879. Paragraph 879 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 879. Mallinckrodt respectfully refers the Court to 18 U.S.C. §§ 1962(c) and (d), which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

880-887. Paragraphs 880-887 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 880-887.

888-889. Paragraphs 888-889 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 888-889. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1341 and 18 U.S.C. § 1343, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

890. Paragraph 890 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 890. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1961(1), 18 U.S.C. § 1341, and 18 U.S.C. § 1343, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

891-896. Paragraphs 891-896 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 891-896.

897. Paragraph 897 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 897. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1341 and 18 U.S.C. § 1343, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

- 898. Paragraph 898 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 898.
- 899. Paragraph 899 asserts legal conclusions and relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

900-901. Paragraphs 900-901 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 900-901. Mallinckrodt respectfully refers the Court to *Travelers Property Casualty Co. of America v. Actavis, Inc.*, 16 Cal. App. 5th 1026, 1030 (2017), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that case.

902-903. Paragraphs 902-903 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 902-903.

904. Paragraph 904 asserts legal conclusions and relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

905. Paragraph 905 merely states Plaintiffs' request for "all legal and equitable relief as allowed by law" to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

SECOND CLAIM FOR RELIEF

Violation of RICO, 18 U.S.C. § 1961 et seq.—Opioid Supply Chain Enterprise (Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen—"RICO Supply Chain Defendants")

- 906. Mallinckrodt incorporates by reference its answers to all other paragraphs with the same legal force and effect as if fully set forth at length herein.
- 907. Paragraph 907 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 907. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1961(3), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

- 908. Paragraph 908 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 908. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1961, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 909. Paragraph 909 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 909. Mallinckrodt respectfully refers the Court to the website quoted in Paragraph 909 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that website or its meaning.
- 910. Paragraph 910 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 910.
- 911. Paragraph 911 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 911. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1961(1), 18 U.S.C. § 1341, and 18 U.S.C. § 1343, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

- 912. Paragraph 912 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 912. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1341 and 18 U.S.C. § 1343, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 913. Paragraph 913 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 913. Mallinckrodt respectfully refers the Court to 21 U.S.C. § 802,4 which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

⁴ Although the Complaint refers to "section 102 of the Controlled Substance Act," this appears to be a typographical error. The Controlled Substances Act does not contain a section 102, and instead contains definitions in section 802.

- 914. Paragraph 914 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 914. Mallinckrodt respectfully refers the Court to 21 U.S.C. § 843(a)(4) and 21 U.S.C. § 843(d)(1), which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 915. Paragraph 915 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 915. Mallinckrodt respectfully refers the Court to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74(b), which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 916. Paragraph 916 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 916. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1961(1), 18 U.S.C. § 1341, and 18 U.S.C. § 1343, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

- 917. No answer is required to Paragraph 917 as it asserts no allegations against Mallinckrodt. To the extent an answer is required, Mallinckrodt does not respond to Plaintiffs' allegations concerning other parties, as Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of those allegations and therefore denies the allegations.
- 918. Paragraph 918 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 918.
- 919. Paragraph 919 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 919. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1341 and 18 U.S.C. § 1343, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 920-925. Paragraphs 920-925 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants," "RICO Supply Chain Defendants," or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 920-925.

- 926. Paragraph 926 asserts legal conclusions and relates to Plaintiffs' characterizations of their claims and thus no answer is required.
- 927-928. Paragraphs 927-928 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 927-928.
- 929. Paragraph 929 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 929.
- 930. Paragraph 930 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt denies any allegations directed at Mallinckrodt.
- 931-933. Paragraphs 931-933 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 931-933.
- 934. Paragraph 934 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations and therefore denies the allegations.

935-936. Paragraphs 935-936 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 935-936.

- 937. Paragraph 937 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.
- 938. Paragraph 938 merely states Plaintiffs' request for "all legal and equitable relief as allowed by law" to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

THIRD CLAIM FOR RELIEF

Violation Of The Ohio Corrupt Practices Act Ohio Revised Code §§ 2923.31, et seq. (Against Purdue, Cephalon, Janssen, Endo, and Mallinckrodt (the "Opioid Marketing Enterprise"))

- 939. Mallinckrodt incorporates by reference its answers to all other paragraphs with the same legal force and effect as if fully set forth at length herein.
- 940. Paragraph 940 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 940. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2923.31(G), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

A. The Opioid Marketing Enterprise and Pattern of Corrupt Activity

- 941. Mallinckrodt incorporates by reference its answers to the paragraphs of Plaintiffs' First Claim for Relief with the same legal force and effect as if fully set forth at length herein.
- 942. Paragraph 942 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 942. Mallinckrodt respectfully refers the Court to Ohio Rev. Code Ann. § 2923.31(C), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 943. Paragraph 943 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 943. Mallinckrodt respectfully refers the Court to Ohio Rev. Code Ann.§ 2923.31(1) and (2), which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 944. Paragraph 944 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the

allegations in Paragraph 944. Mallinckrodt respectfully refers the Court to the 18 U.S.C. § 1341, 18 U.S.C. § 1343, and Ohio Rev. Code Ann. § 2913.05, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

945. Paragraph 945 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" or "Opioid Marketing Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 945.

B. Injury Caused and Relief Sought

946-948. Paragraphs 946-948 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 946-948.

949. Paragraph 949 merely states Plaintiffs' request for "all legal and equitable relief as allowed by law" to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

FOURTH CLAIM FOR RELIEF

Violation Of The Ohio Corrupt Practices Act
Ohio Revised Code §§ 2923.31, et seq.

(Against Defendants Purdue, Cephalon, Endo, Mallinckrodt, Actavis, McKesson,
Cardinal, and AmerisourceBergen) (The "Opioid Supply Chain Enterprise")

950. Mallinckrodt incorporates by reference its answers to all other paragraphs with the same legal force and effect as if fully set forth at length herein.

951. Paragraph 951 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 951. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2923.31(G), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

A. The Opioid Marketing Enterprise and Pattern of Corrupt Activity

- 952. Mallinckrodt incorporates by reference its answers to the paragraphs of Plaintiffs' First Claim for Relief with the same legal force and effect as if fully set forth at length herein.
- 953. Paragraph 953 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 953. Mallinckrodt respectfully refers the Court to Ohio Rev. Code Ann.§ 2923.31(C), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 954. Paragraph 954 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "this Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in

Paragraph 954. Mallinckrodt respectfully refers the Court to Ohio Rev. Code Ann.§ 2923.31(I)(1) and (2), which speak for themselves and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

- 955. Paragraph 955 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 955. Mallinckrodt respectfully refers the Court to 18 U.S.C. § 1961(1)(B) and (D), 18 U.S.C. § 1341, 18 U.S.C. § 1343, and Ohio Rev. Code Ann. § 2913.05, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 956. Paragraph 956 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 956. Mallinckrodt respectfully refers the Court to the Controlled Substances Act, 21 U.S.C. § 821, et seq., which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 957. Mallinckrodt lacks knowledge or information sufficient to form a belief as to the truth of the allegations, and therefore denies the allegations. Mallinckrodt respectfully refers the Court to the document quoted in Paragraph 957 for its complete content, which speaks for itself, and denies any inaccurate characterizations of that document or its meaning.

958-960. Paragraphs 958-960 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 958-960.

- 961. Paragraph 961 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 961. Mallinckrodt respectfully refers the Court to the Corrupt Practices Act, 21 U.S.C. § 843, and 21 U.S.C. § 801, *et seq.*, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 962. Paragraph 962 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 962. Mallinckrodt respectfully refers the Court to the Corrupt Practices Act, 18 U.S.C. § 1341, and 18 U.S.C. § 1343, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 963. Paragraph 963 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 963. Mallinckrodt respectfully refers the Court to the Corrupt Practices Act, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

- 964. Paragraph 964 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 964.
- 965. Paragraph 965 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 965. Mallinckrodt respectfully refers the Court to 21 U.S.C. § 823(a)(1) and (b)(1), and 21 C.F.R. § 1301.74(b)-(c), which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 966. Paragraph 966 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 966. Mallinckrodt respectfully refers the Court to 21 C.F.R. §

1301.11(b) and 21 C.F.R. § 1303.23, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

967-968. Paragraphs 967-968 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" or "Opioid Supply Chain Enterprise" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 967-968.

B. <u>Impact of the Opioid Supply Chain Enterprise</u>

969. Mallinckrodt incorporates by reference its answers to the paragraphs of Section I.G. with the same legal force and effect as if fully set forth at length herein.

C. Injury Caused and Relied Sought

970-972. Paragraphs 970-972 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "RICO Supply Chain Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 970-972.

973. Paragraph 973 merely states Plaintiffs' request for "all legal and equitable relief as allowed by law" to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

FIFTH CLAIM FOR RELIEF⁵

Statutory Public Nuisance (Against All Defendants)

- 974. Mallinckrodt incorporates by reference its answers to all other paragraphs with the same legal force and effect as if fully set forth at length herein.
- 975. Paragraph 975 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt respectfully refers the Court to Ohio Revised Code § 3767.03, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 976. Paragraph 976 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt respectfully refers the Court to Ohio Revised Code § 4729.35, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 977. Paragraph 977 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt respectfully refers the Court to Ohio Revised Code § 715.44, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 978. Paragraph 978 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt respectfully refers the Court to Ohio Revised Code § 3767.01, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

⁵ The Court dismissed the City of Akron's Statutory Public Nuisance claim for lack of standing in its Order on Defendants' Motion to Dismiss, dated December 19, 2018. *See In Re: National Prescription Opiate Litigation*, No. 1:17-MD-2804 at 30-31 (N.D. Ohio Dec. 19, 2018) (order adopting the Report and Recommendation in part, denying in part).

- 979. Paragraph 979 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt respectfully refers the Court to Ohio Revised Code § 4729.35, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 980. Paragraph 980 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt respectfully refers the Court to Ohio Revised Code § 3719.011, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 981. Paragraph 981 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt respectfully refers the Court to Ohio Revised Code §§ 3767.02 to 3767.011, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 982. Paragraph 982 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 982. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 3767.02, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 983. Paragraph 983 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 983. Mallinckrodt respectfully

refers the Court to Ohio Revised Code § 3719.011, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

- 984. Paragraph 984 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 984. Mallinckrodt respectfully refers the Court to Ohio Revised Code §§ 4729.01(F), and Ohio Admin. Code §§ 4729-9-12, 4729-9-16, 4729-9-28, 21 U.S.C.A. § 823, and 21 CFR §1301.74, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.
- 985. Paragraph 985 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 985.
- 986. Paragraph 986 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 986. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2925.02(A), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 987. Paragraph 987 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 987. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2925.02, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

988-992. Paragraphs 988-992 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 988-992.

- 993. Paragraph 993 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations, and therefore denies the allegations in Paragraph 993.
- 994. Paragraph 994 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 994.
- 995. Paragraph 995 merely states Plaintiffs' request for "abatement, recovery of abatement costs, injunctive relief, and to prevent injury and annoyance from any nuisance" to which no answer is required.

996. Paragraph 996 merely states Plaintiffs' request for "all other legal and equitable relief as allowed by law" to which no answer is required.

SIXTH CLAIM FOR RELIEF⁶

Common Law Absolute Public Nuisance (Against All Defendants)

- 997. Mallinckrodt incorporates by reference its answers to all other paragraphs of the SAC with the same legal force and effect as if fully set forth at length herein.
- 998. Paragraph 998 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 998.
 - 999. Paragraph 999 asserts legal conclusions to which no answer is required.

1000-1003. Paragraphs 1000-1003 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1000-1003.

1004. Paragraph 1004 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

⁶ The Court limited Summit County's remedies to injunctive relief in its Order on Defendants' Motion to Dismiss, dated December 19, 2018. *See In Re: National Prescription Opiate Litigation*, No. 1:17-MD-2804 at 30-31 (N.D. Ohio Dec. 19, 2018) (order adopting the Report and Recommendation in part, denying in part).

other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1004. Mallinckrodt respectfully refers the Court to Restatement (Second) of Torts § 821(B), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize the restatement.

1005. Paragraph 1005 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1005.

1006. Paragraph 1006 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations in Paragraph 1006.

1007-1008. Paragraphs 1007-1008 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1007-1008.

1009. Paragraph 1009 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt respectfully refers the Court to Ohio Revised Code § 4729.35, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

1010. Paragraph 1010 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1010. Mallinckrodt respectfully refers the Court to 21 U.S.C.A. § 823, 21 C.F.R. § 1301.74, Ohio Revised Code § 4729.01 (F), and Ohio Admin. Code §§ 4729-9-12, 4729-9-16, and 4729-9-28, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1010.

1011-1012. Paragraphs 1011-1012 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1011-1012.

1013-1015. Paragraphs 1013-1015 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1013-1015.

1016. Paragraph 1016 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1016. Mallinckrodt

respectfully refers the Court to Ohio Revised Code § 2925.02(A), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

1017. The first sentence of Paragraph 1017 was deleted from the SAC and therefore no answer is required. The second sentence of Paragraph 1017 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1017.

1018. Paragraph 1018 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1018.

1019. Paragraph 1019 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1019.

1020. Paragraph 1020 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1020.

1021. Paragraph 1021 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1021.

1022-1028. Paragraphs 1022-1028 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1022-1028.

- 1029. Paragraph 1029 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.
- 1030. Paragraph 1030 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1030.
- 1031-1032. Paragraphs 1031-1032 relate to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations in Paragraphs 1031-1032.

1033-1036. Paragraphs 1033-1036 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1033-1036.

1037. Paragraph 1037 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2307.71, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

1038. Paragraph 1038 merely states Plaintiffs' request for "all legal and equitable relief as allowed by law" to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

SEVENTH CLAIM FOR RELIEF

Negligence (Against All Defendants)

1039. Mallinckrodt incorporates by reference its answers to all other paragraphs of the SAC with the same legal force and effect as if fully set forth at length herein.

1040-1041. Paragraphs 1040-1041 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1040-1041.

1042. Paragraph 1042 legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1042. Mallinckrodt respectfully refers the Court to the Controlled Substances Act, 21 U.S.C. § 821, et seq., which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

1043-1045. Paragraphs 1043-1045 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1043-1045.

1046. Paragraph 1046 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1046.

1047-1050. Paragraphs 1047-1050 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent

"Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1047-1050.

- 1051. Paragraph 1051 asserts legal conclusions to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations in Paragraph 1051.
- 1052. Paragraph 1052 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1052.
- 1053-1054. Paragraphs 1053-1054 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1053-1054.
- 1055. Paragraph 1055 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1055.
- 1056. Paragraph 1056 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1056.

1057. Paragraph 1057 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1057.

1058. Paragraph 1058 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1058. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 4729.35, Ohio Admin. Code §§ 4729-9-12, 4729-9-16, and 4729-9-28, 21 U.S.C. § 823, and 21 C.F.R. § 1301.74, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

1059. Paragraph 1059 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1059.

1060. Paragraph 1060 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient

knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1060. Mallinckrodt respectfully refers the Court to 21 U.S.C. §§ 823, 827(d)(1); 21 C.F.R. §§ 1301.74, 1304.21, 1304.22, and 1304.33(e); Ohio Revised Code §§ 2925.02(A) and 4729.01(F); and Ohio Admin. Code §§ 4729-9-12, 4729-9-16, and 4729-9-28, which speak for themselves, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize such statutes.

1061-1066. Paragraphs 1061-1066 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1061-1066.

1067. Paragraph 1067 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations in Paragraph 1067.

1068-1070. Paragraphs 1068-1070 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1068-1070.

1071. Paragraph 1071 merely states Plaintiffs' request for "all legal and equitable relief as allowed by law" to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

EIGHTH CLAIM FOR RELIEF

Common Law Fraud (Against the Marketing Defendants)

- 1072. Mallinckrodt incorporates by reference its answers to all other paragraphs of the SAC with the same legal force and effect as if fully set forth at length herein.
- 1073. Paragraph 1073 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1073.
- 1074. Paragraph 1074 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1074. Mallinckrodt denies the allegations directed at Mallinckrodt.
- 1075-1077. Paragraphs 1075-1077 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1075-1077.

1078. Paragraph 1078 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1078.

1079-1081. Paragraphs 1079-1081 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1079-1081.

1082. Paragraph 1082 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1082.

1083. Paragraph 1083 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1083.

1084-1085. Paragraphs 1084-1085 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations

pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1084-1085.

1086. Paragraph 1086 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

1087. Paragraph 1087 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1087.

1088. Paragraph 1088 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1088.

1089. Paragraph 1089 merely states Plaintiffs' request for "all legal and equitable relief as allowed by law" to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

NINTH CLAIM FOR RELIEF

Injury Through Criminal Acts (R.C. 2307.60)
(Against All Defendants)

1090. Mallinckrodt incorporates by reference its answers to all other paragraphs of the SAC with the same legal force and effect as if fully set forth at length herein.

- 1091. Paragraph 1091 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1091. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2307.60 (A)(1), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 1092. Paragraph 1092 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1092. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2925.02(A), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 1093. Paragraph 1093 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1093. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2925.02(A)(1), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 1094. Paragraph 1094 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities

other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1094. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2925.02(A)(3), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

1095. Paragraph 1095 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1095. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2925.02, which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

1096. Paragraph 1096 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1096. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2925.02(A)(2), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

1097. Paragraph 1097 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1097. Mallinckrodt

respectfully refers the Court to Ohio Revised Code § 2925.02(A)(2), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

1098-1099. Paragraphs 1098-1099 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1098-1099.

- 1100. Paragraph 1100 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.
- 1101. Paragraph 1101 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1101. Mallinckrodt respectfully refers the Court to Ohio Revised Code § 2307.60(A)(1), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.
- 1102. Paragraph 1102 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1102. Mallinckrodt respectfully refers the Court to the DEA settlement mentioned in Paragraph 1102 for its complete

content, which speaks for itself, and denies any inaccurate characterizations of the DEA settlement or its meaning.

1103-11104. Paragraphs 1103-1104 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1103-1104.

1105. Paragraph 1105 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

1106. Paragraph 1106 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1106.

1107. Paragraph 1107 merely states Plaintiffs' request for "all legal to which they may be entitled" to which no answer is required. Mallinckrodt respectfully refers the Court to Ohio Revised Code §2307.60(A)(1), which speaks for itself, and Mallinckrodt denies any attempt by Plaintiffs to paraphrase or characterize that statute.

TENTH CLAIM FOR RELIEF

Unjust Enrichment (Against All Defendants)

1108. Mallinckrodt incorporates by reference its answers to all other paragraphs of the SAC with the same legal force and effect as if fully set forth at length herein.

- 1109. Paragraph 1109 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1109.
 - 1110. Paragraph 1110 asserts legal conclusions to which no answer is required.
- 1111. Paragraph 1111 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1111.
- 1112. Paragraph 1112 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations. To the extent, "these expenditures" refer to expenditures allegedly caused by Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1112.
- 1113-1119. Paragraphs 1113-1119 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1113-1119.

- 1120. Paragraph 1120 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations in Paragraph 1120.
- 1121. Paragraph 1121 merely states Plaintiffs' request for relief to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations in Paragraph 1121.

ELEVENTH CLAIM FOR RELIEF

Civil Conspiracy (Against All Defendants)

- 1122. Mallinckrodt incorporates by reference its answers to all other paragraphs of the SAC with the same legal force and effect as if fully set forth at length herein.
- 1123-1125. Paragraphs 1123-1125 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1123-1125.
- 1126. Paragraph 1126 asserts legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraph 1126.
- 1126-1134. Paragraphs 1126-1134 assert legal conclusions and allegations that include third parties to which no answer is required. To the extent an answer is required, Mallinckrodt lacks sufficient knowledge or information to form a belief about the truth of the allegations

pertaining to entities other than Mallinckrodt and therefore denies the allegations. To the extent "Defendants" or "Marketing Defendants" pertains to Mallinckrodt, Mallinckrodt denies the allegations in Paragraphs 1126-1134.

- 1135. Paragraph 1135 relates to Plaintiffs' characterizations of their claims and thus no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.
- 1136. Paragraph 1136 merely states Plaintiffs' request for "all legal and equitable relief as allowed by law" to which no answer is required. To the extent an answer is required, Mallinckrodt denies the allegations.

PRAYER FOR RELIEF

- 1137. Mallinckrodt denies the allegations that Plaintiffs are entitled to relief and denies any allegations in the Prayer for Relief.
 - 1138. Any remaining allegations not specifically admitted are hereby denied.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The complaint fails to allege sufficient facts to state a claim upon which relief can be granted, and fails to plead a legally cognizable injury.

Second Affirmative Defense

Plaintiffs have not pled averments of fraud with the required particularity.

Third Affirmative Defense

Plaintiffs' claims are barred in whole or part by the applicable statute of limitations and/or the equitable doctrine of laches.

Fourth Affirmative Defense

Plaintiffs have failed to join one or more necessary and indispensable parties, including without limitation, healthcare providers, prescribers, patients, government agencies, and other

third parties who have engaged in, or failed to reasonably prevent, unauthorized or illicit prescribing, dispensing, diversion, or use of prescription opioid medications or illicit drugs.

Fifth Affirmative Defense

Plaintiffs' claims are barred because they are preempted by federal law and regulation, including by the U.S. Food, Drug, and Cosmetic Act (FDCA), the Controlled Substances Act (CSA), the regulations promulgated pursuant to the FDCA and CSA, and the Supremacy Clause of the United States Constitution. To the extent the Plaintiffs' claims are based on alleged misrepresentations made to the U.S. Food and Drug Administration ("FDA") or Drug Enforcement Administration ("DEA"), such claims are barred pursuant to *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341 (2001).

Sixth Affirmative Defense

Any claims pertaining to generic medicines are preempted, as set forth in the United States Supreme Court's decisions in *PLIVA*, *Inc.* v. *Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceuticals Co.* v. *Bartlett*, 570 U.S. 472 (2013).

Seventh Affirmative Defense

Plaintiffs' claims regarding TIRF Medicines are barred, in whole or in part, by the FDA-approved TIRF REMS Program, including, but not limited to, the requirements imposed on prescribers of TIRF medicines and patients.

Eighth Affirmative Defense

The opioid medications at issue were manufactured, distributed, and labeled in accordance with the provisions of federal law and state law, including the FDCA, the CSA, and the regulations promulgated pursuant thereto.

Ninth Affirmative Defense

Statements in branded or unbranded materials comporting with FDA-approved uses are not misleading as a matter of law or otherwise actionable.

Tenth Affirmative Defense

Plaintiffs' claims are barred and/or this Court should defer this matter to the FDA and/or DEA, in whole or in part, pursuant to the doctrine of primary jurisdiction.

Eleventh Affirmative Defense

Plaintiffs' claims are barred or limited by the separation of powers doctrine.

Twelfth Affirmative Defense

Plaintiffs' improperly joined Mallinckrodt as a Defendant under Rule 20 of the Federal Rules of Civil Procedure because the claims against Mallinckrodt do no arise out of the same transaction, occurrence, or series of transactions as required under Rule 20.

Thirteenth Affirmative Defense

Plaintiffs' claims are barred because Mallinckrodt's conduct conformed with the FDCA, the regulations of the FDA, the CSA, and the regulations of the DEA.

Fourteenth Affirmative Defense

Plaintiffs improperly rely on letters or other informal guidance from the DEA to establish Mallinckrodt's regulatory duties, but informal guidance from the DEA cannot enlarge Mallinckrodt's regulatory duties in the absence of compliance by DEA with the requirements in the Administrative Procedure Act, 5 U.S.C. § 551 *et seq*.

Fifteenth Affirmative Defense

The doctrines of estoppel, including equitable estoppel, and/or waiver bar Plaintiffs' claims.

Sixteenth Affirmative Defense

The representations or statements that Plaintiffs alleged that Mallinckrodt made were true and accurate at the time made and/or otherwise made in good faith, with a reasonable belief as to their validity and accuracy and with a reasonable belief that all conduct was lawful.

Seventeenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by applicable provisions of the United States Constitution and the Constitution of Ohio, including but not limited to the First Amendment to the United States Constitution and Article I, § 11 of the Constitution of Ohio, and applicable provisions of any other State whose laws may apply. In addition, Mallinckrodt's alleged statements are protected as commercial speech and the *Noerr-Pennington* doctrine provides protection for alleged statements in any judicial, legislative, or administrative proceedings.

Eighteenth Affirmative Defense

Plaintiffs' claims are barred by the learned intermediary doctrine.

Nineteenth Affirmative Defense

Plaintiffs' claims are barred by the sophisticated user doctrine.

Twentieth Affirmative Defense

Plaintiffs' claims are barred by the provision of informed consent to patients.

Twenty-First Affirmative Defense

Plaintiffs' common law and public nuisance claims have been abrogated by the Ohio Products Liability Act.

Twenty-Second Affirmative Defense

Plaintiffs' injury through criminal acts claim fails because there has been no relevant criminal conviction.

Twenty-Third Affirmative Defense

Plaintiffs' alleged loss, damage, injury, harm, or expense, if any, was caused in whole or in part by Plaintiffs' ratification of any alleged misconduct, including under the voluntary payment doctrine.

Twenty-Fourth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the doctrines of assumption of risk, contributory negligence, and open and obvious danger.

Twenty-Fifth Affirmative Defense

Plaintiffs have failed to take appropriate and necessary steps to monitor or mitigate any damages.

Twenty-Sixth Affirmative Defense

Plaintiffs may not recover because the methods, standards, or techniques of designing, manufacturing, labeling and distributing the prescription medications at issue complied with and were in conformity with the generally recognized state of the art at the time the product was designed, manufactured, labeled, and distributed.

Twenty-Seventh Affirmative Defense

Plaintiffs' injuries are too speculative and remote from the alleged wrongful conduct to be a basis for liability as a matter of law and due process.

Twenty-Eighth Affirmative Defense

Plaintiffs' claims are moot because the alleged misconduct was not the proximate or legal cause of purported injuries, harm, or damages and/or plaintiffs' injuries, if any, were the result of superseding and/or intervening causes over which defendants had no control. Moreover, the claims set forth in the complaint are barred because the purported injuries, harm, or damages (if

any) were caused, in whole or in part, by plaintiffs' own conduct, and/or that of its contractors or agents, which constitutes superseding and intervening cause(s).

Twenty-Ninth Affirmative Defense

Plaintiffs' claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

Thirtieth Affirmative Defense

Plaintiffs did not show that the users of opioid medications nor their prescribers relied to their detriment upon any statement made by Mallinckrodt in determining to use the medications at issue.

Thirty-First Affirmative Defense

Plaintiffs failed to plead and cannot establish that they incurred any costs, or any injury was caused as a result of, any opioid prescription promoted or sold by defendants that was medically inappropriate or should not have been written, or that any allegedly improper conduct caused any health care provider to write any unnecessary, ineffective or harmful opioid prescriptions.

Thirty-Second Affirmative Defense

Plaintiffs lack standing to bring their claims and to obtain the relief they seek (including for their RICO claims).

Thirty-Third Affirmative Defense

Defendants are not liable for purported injuries, harm, or damages (if any), that were the result of pre-existing conditions or idiosyncratic reactions to medications and/or occurred by operation of nature or as a result of circumstances over which defendants had and continue to have no control.

Thirty-Fourth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the alteration, modification, illicit use or misuse by third parties of the opioid medications at issue.

Thirty-Fifth Affirmative Defense

Plaintiffs' claims are barred to the extent they rely on or implicate the negligent, intentional, malicious, criminal, and/or otherwise unlawful acts or omissions of third parties that are not subject to defendants' control or authority and for which defendants cannot be held liable.

Thirty-Sixth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the Commerce Clause of the United States Constitution, including the Dormant Commerce Clause.

Thirty-Seventh Affirmative Defense

Plaintiffs' claims are barred because they violate procedural and substantive due process rights under the Fourteenth Amendment to the U.S. Constitution and Article I, § § 1, 2, 16, and 19 of the Constitution of Ohio, and the right to be free from retroactive or ex post facto laws as guaranteed by Article I, § 10 of the United States Constitution and Article II, § 28 of the Constitution of Ohio.

Thirty-Eighth Affirmative Defense

Defendants' rights to fair process (including under the Due Process Clause of the U.S. Constitution and Article I, § § 1, 2, 16, and 19 of the Constitution of Ohio) are violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding, including by any use by plaintiffs of a private contingency fee counsel in this action

Thirty-Ninth Affirmative Defense

Plaintiffs' claims are barred, in whole or part, by the free public services doctrine and/or municipal cost recovery rule in that Plaintiffs are not entitled to recover governmental expenditures as a matter of law.

Fortieth Affirmative Defense

Plaintiffs' claims and damages are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a municipality.

Forty-First Affirmative Defense

Plaintiffs' claims are barred or limited by the economic loss rule.

Forty-Second Affirmative Defense

Plaintiffs' claim for unjust enrichment is barred or limited because Defendants did not receive and retain any alleged benefit from plaintiffs.

Forty-Third Affirmative Defense

Plaintiffs have failed to comply with the requirement that they identify each patient in whose claim(s) they have a subrogation interest.

Forty-Fourth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, to the extent they seek to recover any damages, restitution, costs, or other payments that have been reimbursed, paid or borne by other persons or entities.

Forty-Fifth Affirmative Defense

Defendants are entitled to a credit, set-off, or offset for all sums of money received or available from or on behalf of any collateral sources, including tortfeasor(s), for the same injuries alleged in plaintiffs' complaint, including but not limited to any and all settlements Plaintiffs may reach with any tortfeasor(s).

Forty-Sixth Affirmative Defense

To the extent that Plaintiffs' alleged injuries, harm, and/or damages were proximately caused or contributed to by Plaintiffs' own conduct or the conduct of others, defendants are entitled to an individual assessment of fault for each party alleged to have caused any injury, harm, or damage to plaintiffs.

Forty-Seventh Affirmative Defense

Any Defendant's liability must be limited in accordance with the percentage of fault allocated to it by the ultimate trier of fact and/or law.

Forty-Eighth Affirmative Defense

Plaintiffs' claims for punitive damages, statutory damages, civil penalties, and other relief are prohibited under the Fifth, Eighth, and Fourteenth Amendments of the United States Constitution, and Article I § 1, 2, 9, 10, 16, and 19 of the Constitution of Ohio.

Forty-Ninth Affirmative Defense

Plaintiffs are not entitled to recover punitive damages in other litigation over the same course of conduct or that exceed twice the amount of compensatory damages. Plaintiffs are further not entitled to recover punitive or exemplary damages because plaintiffs cannot prove by clear and convincing evidence that Mallinckrodt was grossly negligent and Mallinckrodt has neither acted nor failed to act in a manner that entitles Plaintiffs to recover punitive or exemplary damages.

Fiftieth Affirmative Defense

Plaintiffs are not entitled to attorneys' fees under any applicable provisions of law, including but not limited to Section 54(E) of the Ohio Rules of Civil Procedure.

Fifty-First Affirmative Defense

Plaintiffs are not entitled to any relief in the form of restitution or rescission because they cannot restore the *status quo ante*.

Fifty-Second Affirmative Defense

Plaintiffs' public nuisance claims are barred or limited because, among other reasons, no action of the Defendants involved interference with real property, illegal conduct perpetrated by third-parties involving the use of an otherwise legal product does not involve a public right against the manufacturer sufficient to state a claim for public nuisance, the alleged public nuisance would have impermissible extraterritorial reach, and the alleged wrongful conduct of the defendants is too remote from the alleged "public" injury as a matter of law and due process.

Fifty-Third Affirmative Defense

Plaintiffs' RICO claims are barred, in whole or in part, without limitation, for the following reasons: (1) the absence of the existence of an "enterprise," (2) the absence of the existence of an "association," (3) Mallinckrodt did not participate in any "enterprise," (4) Mallinckrodt did not engage in a pattern of racketeering activity under RICO, (5) Mallinckrodt did not knowingly agree to facilitate any schemes that include the operation or management of a RICO enterprise, (6) the absence of a conspiracy, including a lack of agreement to commit any unlawful predicate acts, (7) Mallinckrodt did not commit any predicate acts, (8) the Federal RICO statute is unconstitutionally vague, (9) Plaintiffs' alleged damages do not constitute injury to business or property interests, and (10) alleged failure to report and halt suspicious orders under the Controlled Substances Act does not qualify as racketeering activity for purposes of RICO.

Fifty-Fourth Affirmative Defense

Plaintiffs' statutory nuisance claim is barred because the statutes upon which Plaintiffs rely, including O.R.C. §§715.44, 3767.01 *et seq.*, are unconstitutionally vague.

Fifty-Fifth Affirmative Defense

Plaintiffs are barred from recovering, in whole or in part, by the doctrine of unclean hands.

Fifty-Sixth Affirmative Defense

Numerous facts would render the imposition of injunctive relief, civil penalties, or other remedies inequitable here, including but not limited to Defendants' good faith reliance on and interpretation of clinical data and medical literature, and the absence of intentional unlawful conduct.

Fifty-Seventh Affirmative Defense

Plaintiffs are not entitled to equitable relief because plaintiffs have an adequate remedy at law and cannot otherwise satisfy the elements for equitable relief.

Fifty-Eighth Affirmative Defense

Plaintiffs have failed to plead or demonstrate any allegations sufficient to support a claim to pierce the corporate veil or to otherwise hold any Mallinckrodt liable merely by virtue of its corporate affiliation with any other Defendant.

Fifty-Ninth Affirmative Defense

Plaintiffs' claims are barred and should be dismissed under Fed. R. Civ. P. 41(b) and any other applicable rules because Plaintiffs have refused to comply with the Court's case management orders, including CMO-1, and because they have refused to identify the allegedly inappropriate, unnecessary, or otherwise improper opioid prescriptions that they contend are at issue and on which they base their claims.

Sixtieth Affirmative Defense

Plaintiffs' claims are barred and should be dismissed as to Mallinckrodt plc because Mallinckrodt plc is an Irish company that has never sold or distributed opioids in the United States or anywhere else and over which no personal jurisdiction exists.

Sixty-First Affirmative Defense

Mallinckrodt adopt by reference any additional applicable defense pled by any other defendants not otherwise pled herein.

Sixty-Second Affirmative Defense

Mallinckrodt intends to rely upon any other defenses that may become available or apparent during the discovery process in this matter (and that may be asserted by other defendants), and hereby reserve its right to amend the list of affirmative defenses and to assert any such defenses.

DEFENSES RESERVED

Mallinckrodt hereby gives notice it intends to rely upon any other defenses that may become available or apparent during the discovery proceedings in this matter and hereby reserves its right to amend its Answer and to assert any such defenses.

DEMAND FOR JURY TRIAL

Mallinckrodt demands a trial by jury and reserves all rights as to the format and structure of any trial to the extent Plaintiffs are permitted to proceed on any of their claims.

Dated: January 15, 2019

/s/ Brien T. O'Connor__

Brien T. O'Connor Andrew J. O'Connor ROPES & GRAY LLP Prudential Tower 800 Boylston St. Boston, MA 02199-3600 (617) 235-4650 Brien.O'Connor@ropesgray.com Andrew.O'Connor@ropesgray.com

Attorneys for Defendants Mallinckrodt LLC and SpecGx LLC

CERTIFICATE OF SERVICE

I hereby certify that on January 15, 2019, a copy of the foregoing **Answer to Plaintiffs' Second Amended Complaint** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

Dated: January 15, 2019

/s/ Brien T. O'Connor__

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